

Before taking an action to revoke a registration, DEA must serve the registrant an order to show cause, which advises the registrant of its right to an administrative hearing before the agency (21 U.S.C. 824(c)). The CSA also gives DEA discretionary authority to suspend any registration simultaneously with the initiation of revocation proceedings in cases where the agency finds there is an imminent danger to the public health and safety (21 U.S.C. 824(d)).

DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion. Moreover, all registrants - manufacturers, distributors, pharmacies, and practitioners - share responsibility for maintaining appropriate safeguards against diversion. Nonetheless, given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm. Accordingly, DEA will use its authority to revoke and suspend registrations in appropriate cases.

The statutory factors DEA must consider in deciding whether to revoke a distributor's registration are set forth in 21 U.S.C. 823(e). Listed first among these factors is the duty of distributors to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. In addition, distributors must comply with applicable state and local law. Congress also gave DEA authority under this provision to revoke a registration based on the distributor's past experience in the distribution of controlled substances and based on "such other factors as may be relevant to and consistent with the public health and safety."

The DEA regulations require all distributors to report suspicious orders of controlled substances. Specifically, the regulations state in 21 C.F.R. 1301.74(b):

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

It bears emphasis that the foregoing reporting requirement is in addition to, and not in lieu of, the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion.

Thus, in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels. Failure to exercise such due diligence could, as circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration.

In a similar vein, given the requirement under section 823(e) that a distributor maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances. Again, to maintain effective controls against diversion as section 823(e) requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling.

In addition, distributors are required to file reports of distributions of certain controlled substances to the DEA ARCOS Unit, in the time and manner specified in the regulations (21 C.F.R. 1304.33). The failure to file ARCOS reports in a complete and timely manner is a potential statutory basis for revocation under section 823(e). Depending on the circumstances, the failure to keep or furnish required records might also be the basis for civil fines or criminal penalties under the CSA provided in 21 U.S.C. 842.

Dkt # 13-1
Govt. Ex. 2
Page 2 of 8

Circumstances That Might Be Indicative of Diversion

DEA investigations have revealed that certain pharmacies engaged in dispensing controlled substances for other than a legitimate medical purpose often display one or more of the following characteristics in their pattern of ordering controlled substances:

1. Ordering excessive quantities of a limited variety of controlled substances (e.g., ordering only phentermine, hydrocodone, and alprazolam) while ordering few, if any, other drugs
2. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered
3. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs
4. Ordering the same controlled substance from multiple distributors

A distributor seeking to determine whether a suspicious order is indicative of diversion of controlled substances to other than legitimate medical channels may wish to inquire with the ordering pharmacy about the following:

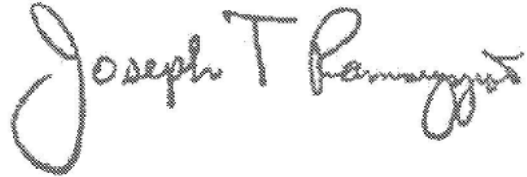
1. What percentage of the pharmacy's business does dispensing controlled substances constitute?
2. Is the pharmacy complying with the laws of every state in which it is dispensing controlled substances?
3. Is the pharmacy soliciting buyers of controlled substances via the Internet or is the pharmacy associated with an Internet site that solicits orders for controlled substances?
4. Does the pharmacy, or Internet site affiliated with the pharmacy, offer to facilitate the acquisition of a prescription for a controlled substance from a practitioner with whom the buyer has no pre-existing relationship?
5. Does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or bona-fide doctor-patient relationship?
6. Are the prescribing practitioners licensed to practice medicine in the jurisdictions to which the controlled substances are being shipped, if such a license is required by state law?
7. Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy?
8. Does the pharmacy offer to sell controlled substances without a prescription?
9. Does the pharmacy charge reasonable prices for controlled substances?
10. Does the pharmacy accept insurance payment for purchases of controlled substances made via the Internet?

These questions are not all-inclusive; nor will the answer to any of these questions necessarily determine whether a suspicious order is indicative of diversion to other than legitimate medical channels. Distributors should consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA will do when determining whether the filling of an order is consistent with the public interest within the meaning of 21 U.S.C. 823(e).

Page 4

We look forward to continuing to work in cooperation with distributors toward our mutual goal of preventing the diversion of pharmaceutical controlled substances.

Sincerely,

A handwritten signature in dark ink, reading "Joseph T. Rannazzisi". The signature is written in a cursive style with a large, looping initial "J".

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

Dkt. # 13-1
Govt. Ex. 2
Page 4 of 8

WAGMDL00757793

HIGHLY CONFIDENTIAL

P-00035_00004

DRUG ENFORCEMENT ADMINISTRATION

September 27, 2006

In reference to registration
PW0122262

P-00035 00005

Before taking an action to revoke a registration, DEA must serve the registrant an order to show cause, which advises the registrant of its right to an administrative hearing before the agency (21 U.S.C. 824(c)). The CSA also gives DEA discretionary authority to suspend any registration simultaneously with the initiation of revocation proceedings in cases where the agency finds there is an imminent danger to the public health and safety (21 U.S.C. 824(d)).

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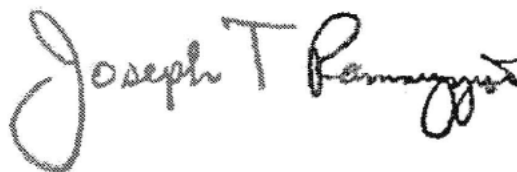
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Page 4

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Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

Dkt. # 13-1
Govt. Ex. 2
Page 8 of 8

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